

Attorney Docket No.: RTS-0339
Inventors: Kenneth W. Dobie
Serial No.: 10/024,396
Filing Date: December 18, 2001
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1. (thrice amended) A compound 8 to 50 nucleobases in length targeted to a 5'-untranslated region, a start codon region, a coding region, a stop codon region, or a 3'-untranslated region of a nucleic acid molecule encoding CD36L1 of SEQ ID NO: 3, wherein said compound specifically hybridizes with one of said regions and inhibits the expression of CD36L1.

REMARKS

Claims 1, 2 and 4-20 are pending in the instant application. Claims 1, 2 and 4-20 have been rejected. Claim 1 has been amended. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Non-Elected Invention

The Examiner suggests that the amendments to claim 1 include reference to new subject matter that was not in any claim that was examined in the Office Action of June 5, 2002 and are thus considered as a non-elected invention. Applicants have amended claim 1, and by dependency claims 2, 4-10 and 12-15, to remove reference to all but SEQ ID NO: 3.

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II. Rejection of Claims Under 35 U.S.C. 102(b)

Claims 1 and 2 have been rejected under 35 U.S.C. 102(b) as being anticipated by Gimeno et al. (US Patent 6,008,014). The Examiner suggests that this patent teaches antisense compounds that target and inhibit expression of CD36L1, including ones that comprise inter-nucleoside, sugar and nucleobase modifications. Applicants respectfully disagree with the Examiner's conclusions regarding this reference.

Gimeno et al. (US Patent 6,008,014) disclose genes encoding lipid metabolic pathway polypeptides and genes encoding those polypeptides. At column 6, lines 49-58, the genes and polypeptides that are the subject of this patent are described as being encoded by cDNAs that can bind to the cytoplasmic domain (amino acids 463-509) of human SR-B1 gene (also known as CD36L1) and that these genes are thus in the same biochemical pathway as SR-B1. However, nowhere does this patent teach or suggest antisense compounds of any type targeted to specific regions of CD36L1, or SR-B1, as suggested by the Examiner. Further, antisense compounds even to the nucleic acid molecules of the patent are only generally disclosed. Nowhere does this patent teach or suggest antisense compounds from 15 to 50 nucleobases in length that target specific regions of the CD36L1 nucleic acid molecule of SEQ ID NO: 3 as

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claimed. In order to anticipate a claim, the reference cited must teach each and every limitation of the claims (MPEP 2131). Accordingly, this patent fails to teach the limitations of the claims and cannot anticipate the instant invention. Withdrawal of this rejection is respectfully requested.

III. Rejection of Claims Under 35 U.S.C. 103(a)

Claims 1, 2 4-10 and 12-15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Gimeno et al. (US Patent No. 6,008,014), in view of Calvo et al. (1993) and Baracchini et al. (US Patent No. 5,801,154). The Examiner suggests that it would have been *prima facie* obvious to one of ordinary skill to make antisense to inhibit CD36L1 because antisense inhibition of this gene was taught by Gimeno et al., the sequence of the gene was provided by Calvo et al., and Baracchini teach the desirability of modifying antisense compounds. The Examiner suggests one of skill would have been motivated to create such compounds due to the teaching of Gimeno et al. regarding the significant of this gene in disease and that Baracchini teach the need for modified oligonucleotides. The Examiner suggests one of skill would have had an expectation of success based on the teachings of Gimeno et

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al. and Baracchini et al. Applicants respectfully traverse this rejection.

As discussed *supra*, Gimeno et al. teach only the general idea of using antisense compounds, and only against genes that are not CD36L1 but instead genes in the same biochemical pathway. No actual inhibition of expression using antisense is disclosed or shown. Further, nowhere does this reference teach or suggest antisense compounds targeted to CD36L1 nucleic acid molecules as claimed, including specific regions of CD36L1 of SEQ ID NO: 3. Therefore, this primary reference fails to teach the limitations of the claims.

The secondary references cited fail to overcome the deficiencies in the teaching of the primary reference.

Calvo et al. (1993) discloses the sequence of CD36L1. Nowhere does this reference teach or suggest antisense compounds of any type targeted to CD36L1 nucleic acid molecules as claimed, including specific regions of CD36L1. Therefore, this reference also fails to teach the limitations of the claims as amended.

Baracchini et al. (US Patent 5,801,154) teaches methods of modifying antisense oligonucleotides to enhance activity. However, nowhere does this patent teach or suggest antisense oligonucleotides 8 to 50 nucleobases in length targeted to CD36L1

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nucleic acid molecules, or any region of a CD36L1 nucleic acid molecule.

To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations. Clearly, the combination of prior art cited fails to teach or suggest the limitations of the pending claims, which claim antisense compounds targeted to specific regions of a nucleic acid molecule encoding CD36L1, and thus cannot render the instant claimed invention obvious. Moreover, a mere teaching of the concept of antisense for a gene other than the one specifically claimed does not give one the expectation of success for using antisense as disclosed in the instant invention. Withdrawal of this rejection is therefore respectfully requested.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

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favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 1 has been amended as follows:

1. (thrice amended) A compound 8 to 50 nucleobases in length targeted to a 5'-untranslated region, a start codon region, a coding region, a stop codon region, or a 3'-untranslated region of a nucleic acid molecule encoding CD36L1 of SEQ ID NO: 3, ~~an exon:exon junction region of a nucleic acid molecule encoding CD36L1 of SEQ ID NO: 12, a 3'-untranslated region of a nucleic acid molecule encoding CD36L1 of SEQ ID NO: 10, an exon:intron junction region, an intron 9 region, an intron 10 region, an intron:exon junction region, an intron 12 region, or an intron 13 region of a nucleic acid molecule encoding CD36L1 of SEQ ID NO: 13,~~ wherein said compound specifically hybridizes with one of said regions and inhibits the expression of CD36L1.